delivery increased FPA levels (12.5 ± 3.5 vs. 2.8 ± 0.6 ng/ml, p = 0.019) compared with patients without events. Patients with events had significantly increased FPA levels prior to (16.9 ± 4.1 vs. 6.1 ± 1.1 ng/ml, p = 0.001) and after PTCA (11.8 ± 3.8 vs. 5.1 ± 1.9 ng/ml, p = 0.03). *Summary:* PTCA in the setting of increased FPA levels was associated with an increased event rate at 6 month follow-up. Intramural delivery of urokinase increased the clinical event rate over a 6 month follow-up. The results support the hypothesis that increased thrombin activity and/or thrombin formation plays a role in restenosis.

802 Stents: Difficult Lesions

Wednesday, March 19, 1997, 4:00 p.m.–5:00 p.m.
Anaheim Convention Center, Arena

4:00

802-1 CPK Rise After Saphenous Vein Graft Intervention: Angiographic Predictors and Clinical Outcomes

S.R. Bailey, D. Snead, R.S. Kiesz, M. Savage, D.L. Fischman, J. Douglas, C. Pepine, J. Werner, R. Rake, S. Goldberg. *The University of Texas Health Science Center at San Antonio, San Antonio, Texas, USA*

Saphenous vein graft interventions (SVGI) are associated with a significant risk of distal embolization and CPK elevation. CPK elevations in native vessels are associated with increased clinical events after interventions. We report the substudy analysis from the Saphenous Vein De novo (SAVED) trial evaluating CPK elevations in the 223 lesions from 220 patients randomized to balloon angioplasty (BA) or Palmaz Schatz (PS) stent.

We evaluated the correlates of CPK elevation stratified as <2×, 2 – 5× and >5× normal. No difference in CPK rise was noted between PS or BA groups. CPK rise correlated with larger vessel size (3.16 ± 0.55 mm vs 3.91 ± 0.72 mm) P < 0.001, and lesions longer than 15 mm (P < 0.01) but not angiographic thrombus or graft age. Balloon to artery ratios were *smaller* and maximal inflation pressures *lower* in patients with CPK elevation. CPK elevation predicted longer hospital stays (5.1 ± 5.4 days vs 12.2 ± 8.2 days, p < 0.01) and an increased risk of death (1/177 <2×, 1/17 >2 <5×, 2/6 >5×, P < 0.001). We conclude that 1) CPK elevation during SVGI occurred more frequently in larger vessels and longer lesions consistent with greater plaque burden. 2) CPK elevation > 5 x normal was associated with more frequent early MI and death. 3) CPK elevation was not related to high pressure inflation over sized balloons or graft age.

4:15

802-2 Contemporary Percutaneous Treatment of Unprotected Left Main Coronary Stenoses – An Update from the ULTIMA Registry

S.G. Ellis, H. Tamai, M. Nobuyoshi, A. Colombo, D.R. Holmes, K. Kosuga, C.L. Grines for the ULTIMA Registry. *Cleveland Clinic Foundation, Cleveland, OH, USA*

Recent single site experience with debulking and stenting of unprotected left main stenoses (ULMS) has led to a re-evaluation of the role of percutaneous treatment (perc rx) in these patients (pts). To amalgamate experience with perc rx of ULMS, we formed a Registry 3/96 and have reported preliminary results (n = 36). The purpose of this report is to update our experience (n = 100), focusing on pt subgroups.

Subgroup	In-hospital Death (%)	6 Month		
		Restenosis (%)	Death (%)	Comp (%)
Stable angina (n = 46)	6.5	29.7	19.6	19.6
Unstable angina (n = 41)	14.6	48.1	39.0	48.7
CABG candidate* (n = 66)	4.6	28.6	16.9	19.0
Refused for CABG* (n = 21)	23.8	85.7	65.0	70.0
Stent* (n = 42)	0.0	33.3	19.0	32.6
DCA* (n = 24)	8.3	21.7	12.5	12.5
Other treatment* (n = 21)	28.6	70.0	47.6	47.9

*excludes pts with acute MI, Comp = cardiac death, MI, or CABG

These preliminary data suggest: 1) when perc rx of ULMS is necessary, stent or DCA is preferred; 2) although stent/DCA for stable angina and CABG candidates gives fair results, except for a 3–5% incidence of sudden death within 6 mos, results with other groups appear unfavorable; 3) Perc rx of ULMS with present technology should be performed cautiously, perhaps with angiographic follow-up at 2–3 mos to identify pts with early (and perhaps life-threatening) restenosis.

4:30

802-3 Chronic Coronary Artery Occlusion: Reduction of Restenosis- and Reocclusion-Rates by Stent Treatment

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Recanalization of chronic coronary artery occlusions by balloon angioplasty is associated with a non-occlusive restenosis rate of about 30% and a reocclusion rate of about 20%. It was the objective of this study to assess restenosis- and reocclusion-rates after stent placement and to determine factors predicting restenosis and reocclusion.

In 143 patients chronic coronary occlusions were recanalized and subsequently treated by stenting. Stentimplantation was performed with high-pressure dilatation (14–18 atm) using mainly Palmaz-Schatz and AVE-Microstents. Medical treatment was with ASA (100 mg/d) in combination with ticlopidine for 4–12 weeks. Control angiography was performed in 120/143 patients 10 to 40 weeks (mean 19 weeks) after successful recanalization. Repeat angiography revealed no restenosis in 87 vessels (72%). Restenosis ≥50% was found in 34 vessels (28%) including reocclusion in 7 vessels (6%). Vessels with restenosis had a significantly smaller minimal luminal diameter (MLD) after stent-implantation as compared to vessels without restenosis (p = 0.03); vessels which were reoccluded at follow-up had a smaller MLD and a smaller reference diameter as compared to vessels without reocclusion (p < 0.03). Symptoms of the patients were markedly improved. At follow-up nearly 80% of patients were asymptomatic whereas prior to intervention more than 70% of patients were in CCS-Class 2 or higher.

Conclusions: 1. Stent treatment of chronic coronary artery occlusion clearly reduces the restenosis and reocclusion rate. 2. Symptoms are markedly reduced or abolished in most of the patients. 3. MLD after the procedure and the diameter of the reference segment were significant predictors of restenosis/reocclusion after stent treatment for chronic occlusions.

4:45

802-4 Stenting in Small Vessels: A Re-evaluation Using the GRII Intracoronary Stent in a Multicenter Registry Study

L.S. Dean, J.P. Zidar, W.D. Voorhees, D.R. Holmes, Jr., C.D. O'Shaughnessy, P.B. Moore, E.W. Rogers, R.R. Heuser, G.S. Roubin, M.B. Leon for the Cook GRII Investigators. *University of Alabama at Birmingham, Birmingham, AL, USA*

Previous experiences using coronary stents in small vessels have produced mixed results. To determine the safety and efficacy of the newly designed GRII stent in small (<3.0 mm) vessels, a multicenter registry was formed and thusfar, 21 centers have enrolled 128 patients. *Clinical demographics:* 62.5% males, mean age 62.4 ± 11.6 years, 32.8% prior MI, 80% de novo lesions, 64.8% multivessel disease, and mean ejection fraction 56.2 ± 11.3%. *Lesion characteristics:* mean vessel diameter 2.6 ± 0.4 mm, lesion length 12.5 ± 8.2 mm, B2 and C lesions 83.6%, diffuse disease 35.2%, and moderate or severe proximal tortuosity 32%. *Procedural details:* stent sizes were 2.5 mm in 36.1% and 3.0 mm in 55.4%. Post-stent high pressure (>14 atm) adjunct PTCA was routinely applied without frequent ultrasound guidance and the routine anticoagulation regimen was aspirin plus ticlopidine. *Results:* Angiographic success was achieved in 99.2% of patients. 30-day clinical outcomes include death in 0.8%, CABG in 0.8%, no Q-wave MI's, subacute stent thrombosis in 3.1%, and repeat PTCA in 2.3%. *In conclusion:* The new GRII stent (1) can be used to treat complex lesions in tortuous small vessels with very high success rates and (2) major adverse events (death, MI, CABG, or repeat PTCA) are infrequent in the first thirty days. Thus, if late follow-up results are similarly favorable, future clinical trials would be indicated to assess the relative value of the GRII stent compared with conventional PTCA in small vessels.